ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Field Quality Engineering Report:
Evaluation Of Reprocessed Ethicon Endo-Surgery Single Patient Use (SPU) Devices
April 4, 2000

EXECUTIVE SUMMARY

A total of 42 reprocessed EES single patient use (SPU) devices were acquired for purposes of conducting engineering analyses and observing the effects of reprocessing and reuse. All devices were received unopened in the reprocessor's packaging. The testing activities are listed in **TABLE 1**. In **Stages 2** and **4** contaminants were analyzed for the presence of blood and tissue, contaminants and/or corrosion products, as appropriate.

TABLE 1 TESTING ACTIVITIES

Stage	Analysis
1	Visual inspection of device in package (exterior)
2	Microscopic inspection of device and package after removal of the device from the package
3	Performance testing to manufacturing quality standards using manufacturing test fixtures
4	Device disassembly and examination by microscope

Recently manufactured EES devices were used as controls in the testing. None of these unused devices exhibited any of the issues discussed below. However, the controls did have residues of lubricants used in manufacture of the products. These materials are biologically safe and were considered acceptable in reprocessed devices also (and not discussed further in this report.)

All reprocessed devices exhibited packaging and or labeling deficiencies, nonconformance to EES quality standards and FDA regulations. Instructions for use, indications, precautions, warnings and contraindications were not provided with any of the devices. Of the reprocessor packaging analyzed, 16 ***(38%)*** occurrences of packaging damage were observed in which the contents of the package was potentially exposed to the environment. These occurrences included tears, punctures and/or damaged seals. These defects compromise the sterile barrier and contradict the reprocessor's assurance of product sterility.

Eleven ***(33%)*** devices were physically damaged and seven were missing components.

Under microscopic examination, 23 (***55%***) devices exhibited biological debris, greasy or gummy residues or particulate matter. On five of these devices, the visible residues tested positive for blood.

Of the nine electrosurgical devices tested, the reprocessor had tampered with five (***56%***) of their electrical insulating sheaths. Of those five, one failed the Dielectric Withstand electrical safety test, posing a risk to the patient or caregiver. The juncture of the original and replaced sheaths represents a weak point in the protective barrier.

Eleven of the 42 devices (***26%***) failed at least one of their product-specific performance tests.

The results from this testing indicate that the practice of reprocessing SPU devices degrades product quality.

1.0 Introduction

In April 1998, an engineering study was conducted at EES on 14 EES SPU devices that had been reprocessed. The reported findings included the observation of tissue debris, dried blood and body fluid on all 14 devices. None of the packages included supporting documentation such as directions for use, precautions, warnings or contra-indications. Electromechanical instruments failed functional testing, and numerous examples of packaging non-conformances and damaged product were also reported. None of these devices would have met EES quality systems acceptance criteria for product release.

Based on the concerns for the risks that may be associated with reprocessing, a plan was created, a protocol written. A request for additional reprocessed devices was issued to specific EES field sales representatives who were seeing the evidence of reprocessing in their areas. The second investigative study commenced in August 1999. The study results indicated that the reprocessing of SPU devices could render them unsafe due to lack of sterility, sub-standard cleanliness and/or degraded performance. Though the study was not yet complete, an interim report was issued in October 1999 to enhance awareness of the situation.

The engineering study has been completed. The scope of this final report is the full 42-device study; data is cumulative. However, this report stresses findings not previously covered. No Figures from the interim report are repeated. The device-specific information is supplemental to the October 1999 report.

2.0 Purpose

The primary purpose of this engineering study was to investigate the effects of reprocessing on EES SPU devices and examine possible degradation in device quality. The evaluation of these devices focused on packaging, product condition and functionality. Of particular concern was that the EES SPU devices in this study were never designed for multi-patient use or to be cleaned effectively for the purpose of reuse. Examining the risks involved with reprocessing of EES SPU devices gained importance due to the increased level of awareness of field reprocessing.

3.0 Materials

Reprocessed EES devices involved in this study were acquired in strict compliance with all applicable guidelines. A wide variety of products (e.g. mechanical, endoscopic, electrosurgery, etc.) was targeted for analysis. A total of 42 instruments was received from the field, representing 24 different product codes. **TABLE 3** contains a complete list of products.

The distribution of received devices by reprocessor is in **TABLE 2**.

New EES devices (same product codes) were tested in sequence with the reprocessed devices to provide a test control for comparison in accordance with good testing practices.

TABLE 2 DISTRIBUTION BY REPROCESSOR

	Alliance Medical	Orris	Vanguard Medical Concepts	Hospital
Devices	**24**	**2**	**11**	**5**

TABLE 3 LIST OF INSTRUMENTS RECEIVED

Tracking #	Type of Instrument	Code
R0001	Modified Allis Clamp, 10 mm	MBA10
R0002	Modified Allis Clamp, 10 mm	MBA10
R0003	Curved Scissors with unipolar cautery	DCS12
R0004	Curved Scissors with unipolar cautery	DCS12
R0005	Curved Dissector with unipolar cautery	DCD32
R0006	Curved Scissors with unipolar cautery	DCD32
R0007	ALLPORT 5mm Multiple Clip Applier	AL326
R0008	ALLPORT 5mm Multiple Clip Applier	AL326
R0009	Stability Sleeve, 10/11 mm, 100 mm	512ST
R0010	Stability Sleeve, 10/11 mm, 100 mm	512ST
R0011	Multiple Clip Applier with rotating shaft, M/L	ER320
R0012	Multiple Clip Applier with rotating shaft, M/L	ER320
R0013	Reloadable Linear Stapler, heavy wire, 90mm	TLH90
R0014	Endoscopic Rotating Clip Appliers	ER320
R0015	Endoscopic Rotating Clip Appliers	ER320
R0016	Trocar sleeve, 12 mm	512SD
R0017	Trocar with dilating tip, 5mm	355LD
R0018	Trocar with dilating tip, 12mm	511SD
R0019	Trocar with stability thread, 12 mm	512B
R0020	Pneumo needle for insufflation	PN120
R0021	Graspers for unipolar cautery (green)	DSG23
R0022	Graspers for unipolar cautery (green)	DSG23
R0023	Graspers for unipolar cautery (green)	DSG23
R0024	Graspers for unipolar cautery (green)	DSG23
R0025	Curved Intralumenal Stapler	CDH21
R0026	LaparoSonic® Coagulating Shears, 15mm	LCS15
R0027	LaparoSonic® Coagulating Shears, 15mm	LCS15
R0028	LaparoSonic® Coagulating Shears, 15mm	LCS15
R0029	ULTRACISION® Coagulating Blade, 15mm	CS150
R0030	ULTRACISION® Coagulating Blade, 15mm	CS150
R0031	PROXIMATE® Linear Cutter, 55mm	TLC55
R0032	Reloadable Linear Stapler, heavy wire, 90mm	TLH90
R0033	Reloadable Linear Stapler, vascular	TLV30
R0034	Trocar with dilating tip	355SD
R0035	ENDOPATH® Trocar, 33mm	LTK33
R0036	ENDOPATH® Trocar , 18 mm	TEC18
R0037	ENDOPATH® Trocar, 18 mm	TEC18
R0038	PROXIMATE® Linear Cutter, 75 mm	TLC75
R0039	PROXIMATE® Linear Cutter, 75 mm	TLC75
R0040	PROXIMATE® Linear Cutter, 75 mm	TLC75
R0041	Endoscopic Linear Cutter, 35 mm	ETS35
R0042	Electrosurgical Scissors	DCS12

4.0 Methods and Scope

An engineering study protocol was created to establish the process. Functional testing followed the same test methods and associated quality requirements currently used in manufacturing as criteria for product release. The Reliability and Development Lab (RDL) system/database was used to coordinate the performance testing and store test data. RDL reports were retained in hardcopy in Field Quality Engineering. A documentation and tracking system was established in which each reprocessed device was catalogued along with source information when it was received. Visual inspection included the use of magnification and photomicrographs where indicated. The RDL microscopist/materials specialist performed chemical testing for blood and other contaminants on residues. Photomicrographs were taken of critical details. Observations, photographs and specific findings were tracked in spreadsheets and kept both in hardcopy and electronically.

Per the engineering study protocol, the testing is defined in four Stages (refer to **Table 1**). Staging the testing assured that all testing was as thorough as possible and that one test does not impact or influence the outcome of the succeeding test.

Due to concern for possible contamination and in conformance with company policy, opened products were handled as if they were field returns. Biological hazard safety precautions were followed.

5.0 References

[1] FQET-005, ***Engineering Study for Testing Reprocessed Single Patient Use (SPU) Products*** (the Protocol)
[2] EES Process and Material Specifications (listed in FQET-005 and/or the RDL Test Reports
[3] RDL Test Reports: Test Request numbers: 9315, 9316, 9317, 9323, 9324, 9331, 9334, 9341, 9413, 9552, 9666, 9671, 9672, 9680
[4] ***Evaluation of Reprocessed Ethicon Endo-Surgery Single Patient Use Medical Devices***, Ethicon Endo-Surgery, Inc., April 1998
[5] ***Evaluation of Ethicon Endo-Surgery Single Patient Use (SPU) Medical Devices***, Ethicon Endo-Surgery, Inc., October 1999

6.0 Definitions

RDL - EES Reliability and Development (test, not clinical) Lab
Process Specifications - manufacturing and in-process test procedures for a product.
Material Specifications - performance criteria a manufactured product must meet when tested in process.
End-Effector - the patient-contact (proximal) end of the device that performs cutting and coagulating. Examples of these are blades, scissors, graspers and hooks for electrosurgical or Harmonic Scalpel® applications.
Tenting - stretching of the package clear plastic film that occurs when a pointed object, upon impact or applied force, has physically strained and weakened the material at the point of contact.

7.0 Observations and Conclusions

Packaging Quality

Most reprocessor packaging consisted of a Tyvek-backed pouch (or double-pouch). Some were wrapped in blue synthetic cloth within a ziplock-type bag. In contrast, EES ships all products in packaging designed to protect the devices and maintain sterility. EES packaging uses a firm, molded plastic to immobilize and cushion the device, protecting the device from potential damage incurred during shipping and handling. Measures such as plastic tips protect the package from pointed end-effectors on a device.

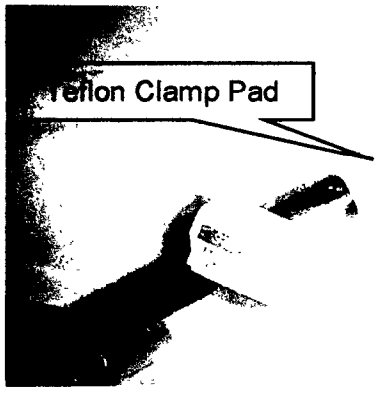
Reprocessor packaging exhibited punctures, seal damage and tears. In many packages, the device was unrestrained (moved freely within the package). The EES plastic protective tips are product-specific in order to fit the tip and remain in place during shipping and handling. Several reprocessed devices that should have had tip protectors either did not have the protectors or the protectors had fallen off in transit. Each of these devices had damaged the seal margin, the Tyvek or the plastic film. Even when devices were double-bagged, damage occurred that created openings in both the plastic film and Tyvek layers.

Double Bagged Linear Cutter Packaging Damage

R0039 Linear Cutter TLC75:
1.5mm Hole in Inner Package

R0039 Linear Cutter TLC75:
1.5mm Hole in Outer Package

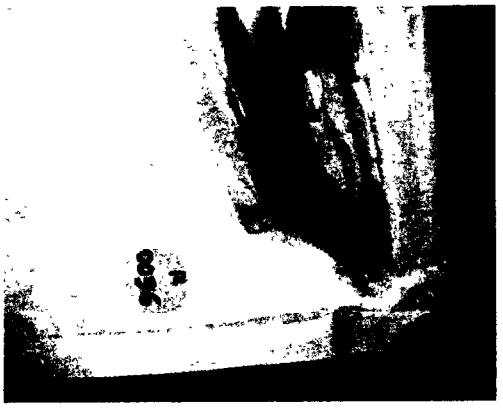
New EES clip appliers, ULTRACISION® end-effectors and electrosurgical devices with pointed distal ends are shipped by EES with the protective tips. The operation of the Harmonic Scalpel® is critically dependent on the surface condition of the end-effectors..



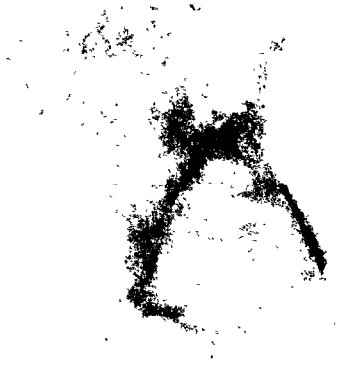
R00029 Harmonic Scalpel® CS150

If a nick or scratch is present on the scissors blade, it may not achieve or maintain resonant frequency. If the Teflon clamp pad is damaged, the scissors may not hold tissue. Customer complaints of "blade won't activate," "constant audible tone" and "generator failure" are often due to blade damage. Complaints of "will not open," "will not close" and "will not hold tissue" are usually indications of clamp pad damage. **NOTE**: Jaw with pad is poking through seam

In addition, tenting of the Tyvek or plastic film occurred near end-effectors, knobs, thumb wheels and other angular or prominent features on the devices. The packaging material was weakened at tented points and therefore susceptible to tearing upon subsequent contact and/or pressure.



R0036 Trocar TEC18
Tip Damaging Seal



R0031 Linear Cutter TLC55
3mm hole in Tyvek

Labeling Issues

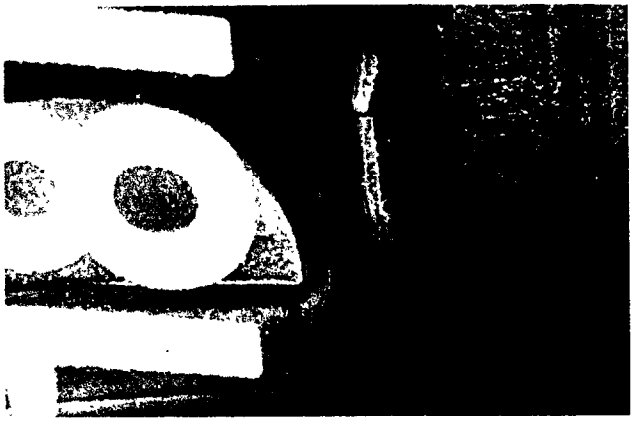
There was no product-specific labeling within the packaging – no instructions, precautions, warnings or contra-indications were included with any of the devices. Several of the packages made statements such as "indefinite shelf life unless opened." Some had no sterilization date on the package. One had no label at all. None gave a shelf-life limitation. All that had exterior labels listed Ethicon Endo-Surgery, Inc, as the manufacturer, however Alliance Medical used the name "Ethicon" which is, in fact, not the company name.

Product Condition

Many of the devices exhibited damage due to surgical usage and/or reprocessing. SPU devices are designed to be used once then discarded.

TOP R0010 Trocar 512ST: Stopcock Broken Off

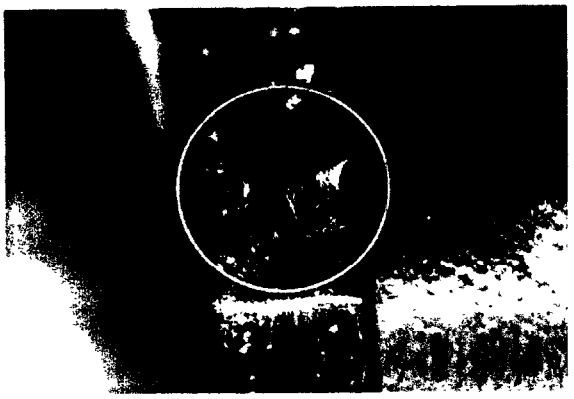
BOTTOM R0036 Trocar TEC18: Crack at Housing/Cannula Joint



Five out of the seven reprocessed trocars exhibited loose or broken and separated stopcocks. As a result, four of the trocars failed the leakage test and could not be expected to support insufflation of the patient. Some of the reprocessed trocars had cracks in the housing-sleeve joint and cracks in the stopcock joint. The trocars are made of injection-molded polycarbonate plastic that is embrittled by repeated exposure to detergents and other ionic cleaning solutions. When exposed to repeated disinfecting and sterilization, the cracks tend to form at corners, joints and other areas of high curvature and tend to propagate with stresses.

During surgery utilizing SPU devices, end-effectors, plastic components or protective coatings or sheaths may be damaged while introducing the device through the trocar or removing the device from the trocar. The reprocessed DCS12 electrosurgical scissors evidenced a bowed shaft and dull and bent scissors. The scissors failed to cut test material.

One of the four reprocessed electrosurgical graspers (DSG23) failed the Dielectric Withstand Test, indicating a safety risk to the patient or the caregiver. After performance testing, the four devices were taken apart and examined in the fault area by microscope. On all four devices, the original sheath had been removed and replaced. In addition, it was found that the sheath of one of the three DCS12 electrosurgical curved scissors had been replaced. The EES sheath material is a fluorinated heat-shrinkable polymer whose dielectric constant is higher than the polyethylene that the reprocessor used as a replacement. The one dielectric breakdown, however, occurred at the juncture of the two materials. The two sheath materials are butted together, as opposed to joined, leaving small gaps.

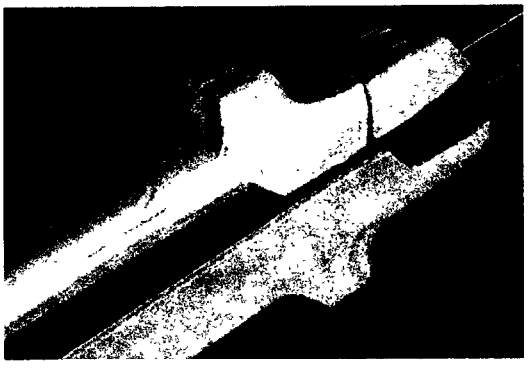


R0023 Electrosurgical Graspers, DSG23:
This picture is of the shaft near the thumbwheel (green) showing the two different black sheath materials.

Notice the melted area (circled) where the dielectric failure had occurred.

R0023 Electrosurgical Graspers, DSG23:
Observe the score marks that were created on the metal shaft of the graspers, probably during the removal of the sheath

One of the reprocessed PROXIMATE® Linear Cutters (TLC75) was sterilized by autoclave with formalin at 65 °C for several hours. The device was warped, partially melted and totally non-functional. Another TLC75 exhibited corrosion on anvil pockets, wear on the knife-edge, cracking and unidentified residues on patient contact parts. In addition, the plastic tip of the cartridge track broke off from the device while the device was being carefully examined. One plastic tip fell off the third reprocessed TLC75 that was examined.

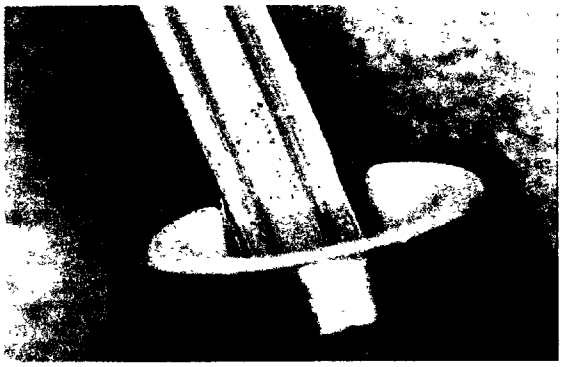


R0038 Linear Cutter TLC75:
Surface marks and deformation were caused by prolonged exposure to high temperature.

R0039 Linear Cutter TLC75:
White plastic tip is shown separated slightly, exhibiting a crack and blood and body fluid residues.

One of the Harmonic Scalpel® LaparoSonic® Coagulating Shears (LCS) showed wear on its coated metallic sheath. Particles of the sheath and black coating lay on the Teflon clamp pad on the upper jaw. Four of the five LCS devices required actuation forces that were **185** to **444%** of the maximum allowed at manufacture. This occurs because the

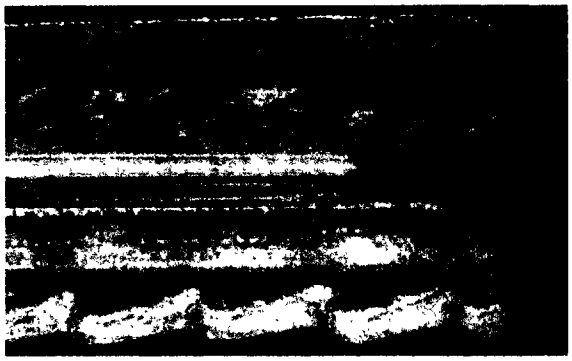
lubricant used inside the handles, sodium stearate, is water-soluble. For the same reason, the reprocessed DCS12 scissors also were difficult to open and close.



R0030 Harmonic Scalpel® LCS15:
Black and metallic particles, from wear of black shaft, can be seen on the Teflon clamp pad

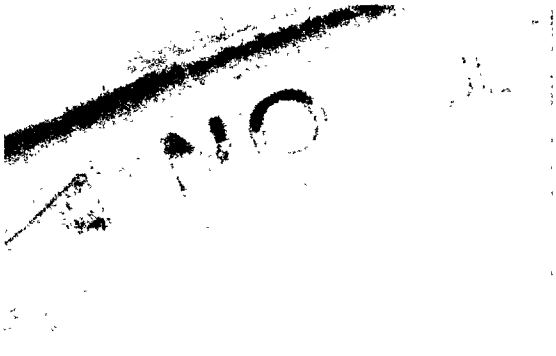
Biological and Environmental Debris

All five of the Harmonic Scalpel® Coagulating Shears and Blades (LCS and CS products) exhibited debris on the patient-contact surfaces. Analysis of residues demonstrated that two of the shears also had blood and tissue on and under the Teflon clamp pad of the jaws.



R0026 LCS15 Harmonic Scalpel® Shears:
Silicone and dried body fluid/tissue are visible on the Teflon clamp pad of the upper jaw.

The four reprocessed electrosurgical graspers (DSG23) all had dirt on their handles inside the recessed labels. In addition, they had customer barcode labels that exhibited dirt and wear. Three of them had residues on their jaws that were identified by testing as copper corrosion products.

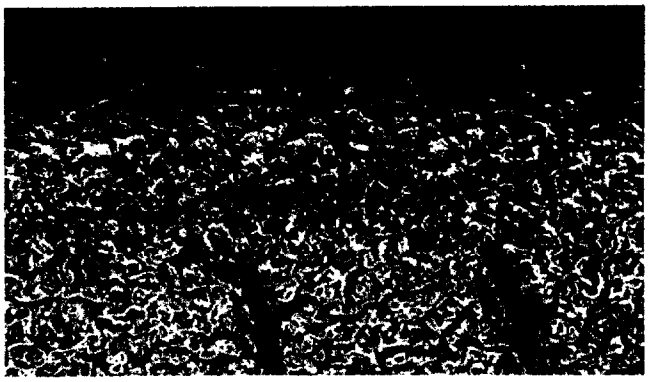


R0023 Electrosurgical Graspers, DSG23
Dirt on handle near ratchet knob contains aluminum flakes.

R0022 Electrosurgical Graspers, DSG23: Residue on jaws consists of corrosion products.

Two of the three reprocessed linear cutters (TLC75) had residues in the anvil, anvil pockets and cartridge channel. Near the patient end of the shaft of the reprocessed ETS35, residues and particulate matter were seen. A curved intraluminal stapler (CDH21) had splotches from a dried liquid (sodium salt of an organic acid?) on the side of its tool holder.

R0018 511SD Trocar:
Inorganic material was seen on obturator safety sheath
The dark areas contain silicone, calcium, chlorine, sodium, magnesium and aluminum. The obturator material is also abraded in those areas.



8.0 Summary

Based on analyses of 42 reprocessed EES SPU devices, none would have met EES quality standards and release criteria. These devices were obtained from hospital shelves and were awaiting use in surgery. The types of nonconformances to EES release criteria are summarized in **TABLE 4** below.

TABLE 4 SUMMARY OF ISSUES

Type of Nonconformance	Number of Nonconformances	
Packaging Damage	16	(38%)
Labeling or Lack of Labeling	42	(100%)
Visible Device Damage	11	(26%)
Failed Performance Tests (all)	11	(26%)
Safety Test	1	(11%)
Blood/Tissue/Contaminants	23	(55%)

- For several packages and several devices more than one defect was observed
- Number in parentheses is percent of all devices except in the case of the safety test which is only performed on electrosurgical devices.

Reprocessors do not appear capable of assessing the condition or proper function of EES products. One reprocessor's attempt to refurbish devices resulted in a patient/caregiver risk condition. Reprocessors' attempts to clean these devices after prior use have also not been adequate. Packaging was found to be substandard in terms of product protection and sterility assurance. Labeling was insufficient, not present or inaccurate -- definitely not compliant with medical device industry regulations. It is therefore concluded that the reuse of these devices poses a significant risk to patients and health care providers.

Pgs. 12-17 were not included in Att. C

Field Quality Engineering Report,
Evaluation of Reprocessed Ethicon Endo-Surgery Single Patient Use Devices
Ethicon Endo-Surgery, Inc.

Date: April, 2000 (supplement to the October 1999 report of the same name)

Objective: To conduct engineering analyses and observe the effects of reprocessing and reuse on single patient use medical devices.

Methods: A total of 42 samples of reprocessed single patient use devices were obtained for study. The sample population was obtained randomly from hospital shelves and included clip appliers, clamps, sleeves, cautery devices, needles, staplers, coagulating hears, trocars and cutters. All samples were assessed for package integrity, product integrity and product performance criteria.

Results: Observed Failures:

Packaging (n=42):	16/42	(38%)
tears, punctures, damaged seals		
Product Quality (n=42):	11/42	(33%)
physically damaged, missing components		
Foreign Material/Contam. (n=42):	23/42	(55%)
biological debris, residues, particulate matter		
five tested positive for blood		

Conclusions: Reprocessing of single patient use devices could render the devices unsafe due to lack of sterility, sub-standard cleanliness and/or degraded performance.